

REMARKS

In response to the Office Action dated August 21, 2009, Applicants respectfully request reconsideration based on the above claim amendments and the following remarks. Applicants respectfully submit that the claims as presented are in condition for allowance.

Claims 1-5, 7-14 and 16-19 are presently pending in the instant Application. Claims 3-5, 7-14 and 16 are withdrawn as being directed to non-elected subject matter in the June 27, 2007 response to Restriction Requirement of June 12, 2007. Claims 1, 2 and 17-19 are amended, and Claims 6 and 15 are cancelled, leaving Claims 1, 2 and 17-19 for consideration upon entry of the present amendment and following remarks.

Support for the claim amendments can at least be found in the specification, the figures, and the claims as originally filed. Specifically, support for the “is formed as channel for containing a sol-gel transformable material” amendment to Claim 1 can be found at least on page 7, lines 10-12. Support for the “intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively” amendment to Claim 1 can be found at least in Claim 6 as originally filed. Support for the “an additional heat source for controlling the temperature of the sol-gel transformable material is absent from the PCR device” can be found at least on page 3, lines 11-13. Further support for this particular amendment can be found at least on page 4, lines 5 – 6.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Claim Rejections Under 35 U.S.C. §112

Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 1, it is stated that the sol-gel transformable material that functions as the microvalves in the instant claims is added to the device at the time of sample addition, and that it is not clear if this material is actually a structure component of the claimed device or merely material worked on by the device.

In the present invention, the sol-gel transformable material that functions as the micro-valves are introduced into the PCR device when PCR is conducted using the PCR device of the present invention. In the PCR device of the present invention, micro-valves for containing a sol-gel transformable material are formed as channels and intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively.

As a result, the Applicants have amended Claim 1 to clarify the present invention.

Support for the amendments to Claim 1 is at least found at least on page 7, lines 10-12, and in Claim 6 as originally filed. Claims 6 and 15 are cancelled.

The Applicants respectfully submit that the amended Claim 1 as well as Claims 2 and 17-19 (which depend from Claim 1) are definite for particularly pointing out and distinctly claiming the subject matter which applicant regards as the invention, and meet the requirements of 35 U.S.C. §112, second paragraph. Entry of the claim amendments, reconsideration and withdrawal of the relevant §112, second paragraph claim rejections are respectfully requested based on the aforementioned amendment to Claim 1.

Claim Rejections Under 35 U.S.C. §102(b)

Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Wilding et al., U.S. Patent No. 5,587,128 (hereinafter “Wilding”). (See Office Action dated 08-21-2009, page 3)

Further, Claims 1, 2 and 17-19 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Mehta et al., U.S. Patent No. 5,306,590 (hereinafter “Mehta”). (See Office Action dated 08-21-2009, page 4) Applicants respectfully traverse the rejections for the reasons set forth below.

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Bariant, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). Moreover, the single source must disclose all of the claimed elements “arranged as in the claim.” *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of

another reference. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

Claim 1 as presently amended is directed to a PCR (polymerase chain reaction) device comprising an inlet through which a biochemical fluid is injected; an outlet through which the biochemical fluid is discharged; a PCR channel positioned between the inlet and the outlet; a heat source for operating the PCR device; and first and second micro-valves which are formed as channel for containing a sol-gel transformable material, wherein the first and second micro-valves control opening and closing of the inlet and the outlet, and intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively; wherein the sol-gel transformable material transforms from a sol state into a gel state at a temperature lower than DNA denaturation temperature, annealing temperature and extension temperature and higher than room temperature, as the temperature increases to operate the PCR by the heat source; and is operative to control the opening and closing of the first and second micro-valves; and wherein an additional heat source for controlling the temperature of the sol-gel transformable material is absent from the PCR device.

The invention of Claim 1 has micro-valves, which are formed as channels. The micro-valves are for containing the sol-gel transformable material. The micro-valves intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively. The sol-gel transformable material introduced in the micro-valves can transform from a sol state into a gel state by the heat source for operating the PCR device during the PCR operation (*i.e.*, DNA denaturation, annealing and extension). Therefore, the PCR device of Claim 1 does not require an additional heat source for controlling the temperature of the sol-gel transformable material.

Wilding discloses only a mechanically operative valve (col. 23, lines 37-39). Wilding does not disclose a valve formed as channel for containing a sol-gel transformable material. Since the micro-valves formed as channel are operative constituents of the present invention, these elements should be considered. Therefore, the invention of Claim 1 is different from the invention of Wilding.

The case law cited by the Examiner is erroneous and does not apply to the claimed invention at hand. The case law cited by the Examiner, notably that from *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) where it is stated that “[E]xpressions relating the apparatus to

contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim” is inappropriate. In the present invention, the sol-gel transformable material are actually operative to permit the material to flow through the channels. The sol-gel transformable material are not just materials contained in the apparatus during its operation. The sol-gel materials functions in a particular manner and the manner in which it functions distinguish the valve from those valves prescribed by Wilding. Consequently, the PCR (polymerase chain reaction) device of Claim 1 is distinguishable over the device taught by Wilding. Wilding thus does not teach all elements of the claimed invention. The Applicants respectfully request a withdrawal of the anticipation rejection and an allowance of the claims.

Mehta only discloses a fluid connection which are unvalved or electrically gated(col. 4, lines 18-21). Mehta does not disclose a valve formed as channel for containing a sol-gel transformable material. Further, Claim 1 is amended to incorporate previous Claim 6, which is not rejected as being allegedly anticipated by Mehta. For at least two reasons, Mehta thus does not teach all elements of the claimed invention. Since neither Mehta nor Wilding teach all elements of the claimed invention, the Applicants respectfully request a withdrawal of the anticipation rejection and an allowance of the claims.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Blackburn, U.S. Patent No. 6,875,619 (hereinafter “Blackburn”) in view of Robotti et al., U.S. Patent Application Publication No. US 2002/0054835 (hereinafter “Robotti”). (See Office Action dated 08-21-2009, page 6)

Applicants respectfully traverse the rejections for the reasons set forth below.

The Supreme Court has recently reaffirmed the principle that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art.... This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Court further stated that “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). However, “the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* And the Court expressly encouraged the use of common sense in such analysis. *Id.* Finally, the Court agreed that the teaching-suggestion-motivation test (“TSM test”) captured a helpful insight to prevent hindsight bias, but the Court held that “[h]elpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents.” *Id.*

As mentioned above, the invention of Claim 1 has micro-valves which are formed as channels. The micro-valves are formed to contain the sol-gel transformable material. The micro-valves intersect portions of the PCR channel near the inlet and the outlet of the PCR device, respectively. Further, according to the invention of Claim 1, the sol-gel transformable material introduced in the micro-valves can transform from a sol state into a gel state by the heat source for operating the PCR device during the PCR operation (*i.e.*, DNA denaturation, annealing and extension). Therefore, the PCR device of Claim 1 does not require an additional heat source (that supplies heat directly to the micro-valve) for controlling the temperature of the sol-gel transformable material.

Blackburn is directed to a variety of microfluidic devices with configurations that include the use of biochannels or microchannels comprising arrays of capture binding ligands to capture target analytes in samples. (see Abstract) Blackburn does not teach a valve having a gel that can reversibly change its state to permit the valves to open and close.

In Blackburn, the fluid flow control system 30-34 shown in Fig. 8 can comprise electroosmotic pumping systems or capillary stop valves (col. 54, line 65 ~ col. 55, line 10). In order to control these valves, electric power or a high pressure is required. However, the valves of the present invention do not require electroosmotic pumping systems or the capillary pressure. The valves of the present invention are formed as channels that contain the sol-gel transformable material. In order to control the valves of the present invention, heat is required. Such features of the present invention are not disclosed in Blackburn. In short Blackburn does not teach sol-gel operated valves and in addition the system disclosed by Blackburn does not provide the heating device needed for operation of a sol-gel transformable material valve.

Further, in Blackburn, the valve 34 is connected to a recirculating arm 33 as shown in Fig. 6 (col. 9, lines 23-26). The structure of the valve in Blackburn is different from that of the present invention wherein the valves formed as channels intersecting portions of the PCR channel near the inlet and the outlet of the PCR device, respectively. This features of the present invention are not disclosed in Blackburn.

[Fig. 6 of Blackburn]

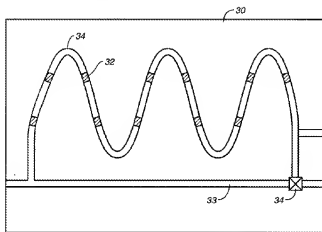


FIG. 6

In Robotti, a thermoreversible gel is used. However, in Robotti, the micro-valve region is directly over a heating element (paragraph [0049]) in order to apply heat to the valve. Therefore, there should be a heating element 15 below every micro-valve 18 as shown Fig. 2 in Robotti.

[Fig. 2 of Robotti]

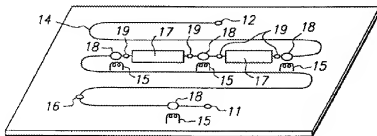


FIG. 2

However, in the present invention, the heat source for operating the PCR device is used as it is, and no additional heat source is required for controlling the temperature of the sol-gel transformable material introduced in the micro-valves in the present invention. In short, in the claimed invention, the entire PCR device contains a source of heat and each valve does not contain a resistive heater such as heater 15 shown in the Figure 2 of Robotti. The presence of a single heater for the entire PCR device without individual heaters is neither disclosed by Blackburn nor Robotti.

The Applicants respectfully request that the constitutional element that “an additional heat source for controlling the temperature of the sol-gel transformable material is absent from the PCR device” in the negative limitation in Claim 1 should be considered according to MPEP 2173.05(i), especially since there is support for this negative limitation in the specification as originally filed.

In addition, there is no motivation to combine Blackburn with Robotti since Robotti now teaches away from the claimed invention. As noted above, the claimed invention does not require the presence of individual heaters located near each valve as prescribed by Robotti. Robotti, in not requiring a single heater for the entire PCR device and instead teaching a plurality of heaters, each being located proximate to a valve teaches away from the claimed invention. Case law holds that “[O]bviousness can be rebutted by showing that “the prior art teaches away from the claimed invention.” *In re Geisler*, 116 F.3d 1465, 1471 (Fed. Cir. 1997).

Since Robotti teaches away from the claimed invention, there is no motivation for one of ordinary skill in the art to combine Robotti with Blackburn. Even if Robotti were to be combined with Blackburn, the combination would not produce the claimed invention.

Since neither Blackburn nor Robotti disclose the presence of a heat source for operating the entire PCR device, the Applicants believe that these references even when combined do not teach all elements of the claimed combination. The Applicants believe that the Examiner has not made a prima facie case of obviousness over Blackburn even when combined with Robotti. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Claims 1, 2, 6, 15 and 17-19 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Blackburn in view of Robotti taken further in view of Yang et al., U.S. Patent No. 6,382,254 (hereinafter "Yang"). (See Office Action dated 08-21-2009, page 8)

As noted above, neither Blackburn nor Robotti teach all elements of the claimed invention. In particular, since neither Blackburn nor Robotti disclose the presence of a heat source for operating the entire PCR device, the Applicants believe that these references even when combined do not teach all elements of the claimed combination.

In Yang, a heater 35 is also provided for heating the valve as shown in Fig. 1 (col. 3, line 62 ~ col. 4, line 20).

[Fig. 1 of Yang]

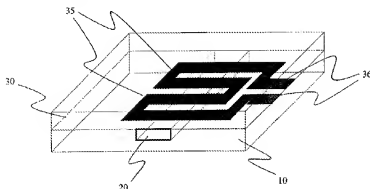


Fig 1

While Yang does teach the presence of a centralized heater, the combination of Blackburn, Robotti and Yang would require the presence of two sets of heaters – notably that prescribed by Yang as well as those prescribed by Robotti. However, in the present invention, the heat source for operating the PCR device is used as it is, and no additional heat source is required for

controlling the temperature of the sol-gel transformable material introduced in the micro-valves of the present invention.

Thus, when Blackburn, Robotti and Yang are taken in combination, there will be an additional heat source for controlling the valve in addition to the heat source for operating the PCR device. However, the claimed invention does not require an additional heat source for controlling the valve.

If the Examiner suggests removing the valves from Robotti, the Examiner would be modifying Robotti in such a manner so as to change the mode of operation of Robotti. In this regard, the courts have held that “[i]f the proposed modification would render the prior art invention being modified unsatisfactorily for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon* 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The courts have also held that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” *In re Ratti* 270 F. 2d 810, 123 USPQ 349 (CCPA 1959).

In summary, as all elements of Claim 1 are not disclosed in Blackburn, Robotti and Yang, taken alone or in combination, Claim 1 and dependent Claims 2 and 17-19 cannot be obvious over the combination of references. The Applicants respectfully request a withdrawal of the obviousness rejection and an allowance of the claims.

Entry of the claim amendments, reconsideration, withdrawal of the relevant §103(a) rejections and allowance of Claims 1-15 are respectfully requested.

Conclusion

In view of the foregoing, it is respectfully submitted that the instant application is in condition for allowance. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance issued. If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned.

In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicants' attorney hereby authorizes that such fee be charged to Deposit Account No. 06-1130.

Respectfully submitted,

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Date: November 17, 2009